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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/679,664   | 10/03/2000  | Thomas M. Stormann   | 072827-1801         | 7662             |
| 24247  | 7590        | 02/13/2006           | EXAMINER            |                  |
| TRASK BRITT<br>P.O. BOX 2550<br>SALT LAKE CITY, UT 84110 |             |                      | LANDSMAN, ROBERT S  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1647                |                  |

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/679,664             | STORMANN ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Robert Landsman        | 1647                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 January 2006.

2a) This action is **FINAL**.                                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-11 and 42-62 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-11 and 42-62 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
  .Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
  Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION*****1. Formal Matters***

- A. The Amendment filed 1/25/06 has been entered into the record.
- B. Claims 1-11 and 42-62 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

***2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

- A. Claims 1-11 and 42-62 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2-4 of the Office Action mailed 10/20/05. Applicants argue that, “to be enabling, ‘the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.’ ‘A patent need not teach, and preferably omits, what is well known in the art.’ In addition, ‘detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.’ ‘The test for determining enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.’”

To this effect, Applicants argue that the specification discloses various domains of the claimed proteins and that, therefore, there is support for “75% identity” and that these domains and variants can be readily produced from information in the art. Applicants also argue that the specification teaches how to identify amino acids not necessary for receptor activity and how to substitute conservative amino acids into the proteins. Finally, Applicants argue that the specification provides general guidance on producing and testing derivatives of amino acid sequences that are at least 75% identical to CaR, mGluR, or GABABR to determine whether these proteins are biologically active.

These arguments have been considered, but are not deemed persuasive. First, the disclosure of this application is not sufficient to inform those skilled in the art how to make the claimed invention. Applicants have claimed fusion proteins which are comprised of up to three distinct proteins, each region (intracellular, transmembrane and extracellular) can have as much as 25% variation compared to a wild-type protein region (i.e. 75% identity). Respectfully, though the specification may teach how to identify amino acids necessary for receptor activity, the specification has not provided sufficient, if any, guidance and working examples of these amino acids. The specification only discloses that techniques well-known

in the art can be used to identify these residues. Similarly, though the specification discloses that conservative substitutions may be made in the protein regions, the claims are not limited to these substitutions, nor is it guaranteed that a simple charge-for-charge substitution would be sufficient to retain protein activity. If this were the case, there would only need to be 3 naturally occurring amino acids – a positively charged, a negatively charged and a neutral amino acid. It is, therefore, clear that the side groups found on the individual amino acids are responsible for the structure and function of the proteins and a simple substitution is no guarantee that a protein will retain its function.

Though Applicants argue that a patent preferably omits what is known in the art, this is no sufficient for the present situation. The present claims are drawn to proteins with up to 75% of the protein altered. It would not be predictable to the artisan which residues to alter to retain the function of the wild-type protein. Therefore, this information should not be omitted from the specification, since this specific guidance is needed. Regarding Applicants' argument that the specification provides general guidance on producing and testing derivatives of amino acid sequences that are at least 75% identical to CaR, mGluR, or GABABR to determine whether these proteins are biologically active – the standard for enablement is “make and use,” not “make and test.”

### ***3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

A. Claims 1-11 and 42-62 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action mailed 10/20/05. Applicants arguments are identical to those argued above for enablement. Therefore, the rejection is maintained for the reasons as discussed above by the Examiner. Applicants' argument that “the description need only describe in detail that which is new or not conventional” and “what is conventional or well-known to one of ordinary skill in the art need not be disclosed in detail” is not persuasive since making changes to a protein to alter it as much as 25% is not conventional and details would need to be provided, as discussed in the above enablement rejection. It is believed that all pertinent arguments have been addressed.

### ***4. Conclusion***

A. No claim is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on T-F 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert Landsman  
Primary Examiner  
Art Unit 1647